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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,313	06/21/2001	Alexander Michael Chagovetz	46641-01010	5607

7590 06/26/2003

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	16

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,313	CHAGOVETZ, ALEXANDER MICHAEL	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Information Disclosure statement (Paper No. 3) filed on September 24, 2001 has been entered and considered.

2. Applicant's election with traverse of Group I (claims 1-18) (Paper No. 15) is acknowledged. The traversal is on the ground(s) that examining both the groups would not be a serious burden, since search for art relating to one group would result in art relating to the other group. This is not found persuasive because of the following reasons: (i) search for one group not necessarily result in art related to another group (ii) separate classification search is prima facie evidence of burden, (iii) the issues are not the same with respect to 35 U.S.C. 112 and 35 U.S.C. 101 statutes, (iv) separate Art units would examine the two Groups under ordinary circumstances. Hence the restriction requirement is still deemed proper.

3. Claims 1-18 are considered for examination in this office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims 1 and 17 recite " forming a nucleic acid / forming a primer pair" which is unclear and indefinite because the term "forming" is unclear for whether it refers to obtaining or synthesizing or isolating or producing. Further the instant claims recite measuring device, which is not clear whether the device refers to electrophoretic detection device or

hybridization or colorimetric or spectrophotometric device. Amendment to clarify the word would obviate this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 6-15, are rejected under 35 U.S.C. 102(e) as being anticipated by Nazarenko et al. (USPN. 6,090,552).

With reference to the instant claims 1 and 6, Nazarenko et al. teach a method for detecting a nucleic acid target sequence in a sample wherein Nazarenko et al. disclose that the method comprises (a) obtaining or forming a nucleic acid target sequence (see column 14, lines 29-32, column 49, lines 27-32); (b-d) synthesizing or forming a primer pair for amplifying said target sequence in a polymerase chain reaction wherein the forward and reverse primers are labeled (see column 29, lines 51-61, column 14, lines 29-53, column 13, lines 26-34, column 18, lines 22-35); (e) introducing a quantity of said forward and reverse primers , a quantity of Taq polymerase, dNTPs, and a quantity of said target sequence in an aqueous reaction medium, in a reaction vessel (see column 29, lines 62-67, column 14, lines 53-54, column 49, lines 42-51); (f) initiating the polymerase chain reaction, producing a double stranded amplification product,

wherein the amplification reaction comprises incorporated primers producing a signal upon energy stimulus and detecting the signal using gel electrophoresis and spectroflurophotometer (see column 30, lines 11-13, column 41, lines 12-16, column 51, lines 59-67).

With reference to the instant claims 1-5, 7-15, Nazarenko et al. also discloses that the method comprises (i) first and second dyes as fluorescent energy transfer dyes comprising donor and acceptor flurophores and signal is generated by FRET (see column 29, lines 51-67, column 30, lines 1-13, column 14, lines 29-53, column 6, lines 17-23, column 3, lines 43-56); (ii) FRET moieties are separated by 15-25 nucleotides (about 100 A^0) (see column 24, lines 57-64); (ii) target sequence includes a mutation point, primers are designed to flank the mutation point and amplification product includes a copy of said mutation point (column 56, lines 10-35, column 57, 12-44); (iii) signal is analyzed to determine the length of said target sequence (see column 49, lines 1-6); (iv)control sample comprises with no DNA (see column 51, lines 38-39). Nazarenko et al. also disclose that the method can be used for multiplex analysis in which several targets are amplified in the same reaction (see column 49, lines 12-19). Thus the disclosure of Nazarenko et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarenko et al. (USPN. 6,090,552) and in view of Herrewegh et al. (J Clin Microbiol., Vol. 33(3), pp. 684-689, 1995).

Nazarenko et al. teach a method for detecting a nucleic acid target sequence in a sample wherein Nazarenko et al. disclose that the method comprises (a) obtaining or forming a nucleic acid target sequence (see column 14, lines 29-32, column 49, lines 27-32); (b-d) synthesizing or forming a primer pair for amplifying said target sequence in a polymerase chain reaction wherein the forward and reverse primers are labeled (see column 29, lines 51-61, column 14, lines 29-53, column 13, lines 26-34, column 18, lines 22-35); (e) introducing a quantity of said forward and reverse primers , a quantity of Taq polymerase, dNTPs, and a quantity of said target sequence in an aqueous reaction medium, in a reaction vessel (see column 29, lines 62-67, column 14, lines 53-54, column 49, lines 42-51); (f) initiating the polymerase chain reaction, producing a double stranded amplification product, wherein the amplification reaction comprises incorporated primers producing a signal upon energy stimulus and detecting the signal using gel electrophoresis and spectroflurophotometer (see column 30, lines 11-13, column 41, lines 12-16, column 51, lines 59-67).

Nazarenko et al. also discloses that the method comprises (i) first and second dyes as fluorescent energy transfer dyes comprising donor and acceptor fluorophores and signal is generated by FRET (see column 29, lines 51-67, column 30, 1-13, column 14, lines 29-53, column 6, lines 17-23, column 3, lines 43-56); (ii) FRET moieties are separated by 15-25 nucleotides (about 100 A^0) (see column 24, lines 57-64); (ii) target sequence includes a mutation point, primers are designed to flank the mutation point and amplification product includes a copy

of said mutation point (column 56, lines 10-35, column 57, 12-44); (iii) signal is analyzed to determine the length of said target sequence (see column 49, lines 1-6); (iv) control sample comprises with no DNA (see column 51, lines 38-39). Nazarenko et al. also disclose that the method can be used for multiplex analysis in which several targets are amplified in the same reaction (see column 49, lines 12-19). However Nazarenko et al. did not teach target sequence comprising a length of upto 130 nucleotides and range from 25 nucleotides to about 100 nucleotides, mRNA and using forward primer to produce a cDNA.

Herrewegh et al. teach a method for reverse transcriptase PCR wherein Herrewegh et al. disclose that the method comprises (i) target nucleic acid comprising a length ranging from 35 up to 177 bp (see page 685, column 2, paragraph 3) (ii) and preparing RNA and reverse transcribing RNA with a premix comprising a primer used for PCR to produce cDNA (see page 685, column 1, paragraphs 1-5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting a target nucleic acid as taught by Nazarenko et al. with the method as taught by Herrewegh et al., because Herrewegh et al. et al. states that 'the new RT-PCR method is used to improve sensitivity of detecting viral RNA (see page 686, column 1, paragraph 6). An ordinary practitioner would have been motivated to combine the method of detecting a target nucleic acid sequence as taught by Nazarenko et al. with the method as taught by Herrewegh et al. in order to achieve the expected advantage of a rapid and sensitive method for detecting nucleic acid samples including RNA, because inclusion of RT-PCR limitation would enhance the utility of the assay in detecting any sample comprising DNA or RNA.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
June 13, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER